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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,551	01/08/2001	Casey D. Morrow	UAI-004CPDV2CN	6750
25225	7590	06/08/2005	EXAMINER	
MORRISON & FOERSTER LLP 3811 VALLEY CENTRE DRIVE SUITE 500 SAN DIEGO, CA 92130-2332			WOITACH, JOSEPH T	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/756,551	Applicant(s) MORROW ET AL	
	Examiner Joseph T. Woitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49 and 51-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49, 51-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a continuation of 09/376,184, filed August 17, 1999, now abandoned, which is a continuation of 08/987,867, filed December 9, 1997, now patent number 6,063,384, which is a continuation of 08/389,459, filed February 15, 1995, now patent number 5,817,512, which is a continuation of 08/087,009, filed July 1, 1993, now abandoned.

Applicants' amendment filed March 24, 2005, has been received and entered. Claims 1-48 and 50 have been cancelled. Claims 49, 52, 55 and 56 have been amended. Claims 49, 51-63 are pending and currently under examination as they are drawn to a method of expressing a foreign gene in a cell both *in vivo* and *ex vivo*.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49, 51-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 49 has been amended to recite "substantially free" however neither the claim nor the specification provide parameters of what is considered substantially free. It is in part confusing because the claim does not require that an unmodified poliovirus be used in the claimed methodology. More importantly, even if a unmodified poliovirus is used to make an encapsidated recombinant poliovirus, the metes and bounds are indefinite because the skilled artisan can not determine how much or how little of the unmodified

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poliovirus can be present and still be considered a substantial amount. Claims 51-63 depend on claim 49 and fail to further clarify the basis of the rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49 and dependent claims 51-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Specifically, claim 49 has been amended to recite that the "composition is substantially free of unmodified poliovirus" and Applicants point to page 4 for support of the amendment. Initially, upon review of page 4, and the specification in total Examiner can not find literal support for the claimed amendment. On page 4, support for the positive statement of "substantially comprises encapsidated recombinant poliovirus nucleic acid" is found, however this support only a nucleic acid, and fails to support what one of skill in the art would consider substantial. Moreover, in light of the teachings of the specification the amendment at best would only support providing such a composition with the specific methodology discussed on page 4, lines 3-16.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 49, 51-63 are also rejected under 35 U.S.C. 112, first paragraph, as

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containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described. More specifically, the specification provides one specific methodology of encapsidating recombinant poliovirus and fails to provide guidance to a general functional limitation encompassed by the claim.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 49, 53, 55, 57, 61 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Choi *et al.* is withdrawn.

Applicants note the amendments to the claims to include the embodiment of claim 50 (not part of the original rejection) and that the gene product be therapeutic, and argue that as amended Choi *et al.* fail to anticipate the invention. See Applicants' amendment, page 5. Applicants' arguments have been fully considered and found persuasive.

Examiner agrees that while the HIV-1 sequence could be considered therapeutic in light of the teachings of the instant specification, Choi *et al.* fail to teach an encapsidated recombinant poliovirus genome (previously claim 50).

Claims 49, 53, 55, 57 and 61 rejected under 35 U.S.C. 102(a) as being anticipated by Percy *et al.* is withdrawn.

Applicants note the amendments to the claims in particular that the composition be free of unmodified poliovirus and that the gene product be therapeutic, and argue that as amended Percy *et al.* fail to anticipate the invention. See Applicants' amendment, page 5. Applicants' arguments have been fully considered and found persuasive.

Specifically, Examiner agrees that the teaching of Percy *et al.* to insert the CAT reporter gene into the vector fails to provide anticipation for a therapeutic gene. However, it is noted that Applicants' arguments that the composition is substantially helper virus is not found convincing,

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in particular since each round of infection to provide infection particles required the addition of helper virus 5PFU/cell (see page 5044, first column). If the composition was substantially helper virus, the addition of the helper virus would not be necessary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 49-62 rejected under 35 U.S.C. 103(a) as being unpatentable over Barber *et al.* (US Patent 5,662,896), Percy *et al.* and Choi *et al.* is withdrawn.

As discussed above, neither Percy *et al.* nor Choi *et al.* provide the necessary teaching to anticipate the independent claims as amended, and the teachings of Barber *et al.* fails to remedy these deficiencies. However it would be maintained that Barber *et al.* specifically contemplate the use of polioviral vectors (column 10, lines 44-47), and that one of skill in the art would be motivated to use polioviral vectors demonstrated in the art to be useful for delivery, in particular for the for cancer immunotherapy where a combination of antigens and/or cytokines are expressed using vectors delivered to a patient as taught by Barber *et al.* (see for example

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summary of invention, section starting in column 6, line 16, and claims 1-4). However, there is no such teaching even in Percy *et al.* who discuss the use of their encapsidated recombinant polio virus constructs for studying the polio virus sequences itself, not as general a delivery vector for gene therapy.

Conclusion

No claim is allowed. The newly amended claims are free of the art of record because the fail to teach all the limitation required by the claims. While the work of both Percy *et al.* and Choi *et al.* provide the starting point for the claimed invention, the invention as now claimed differentiates itself from the art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

Joe Woitach
AUG 32